

Serial No. 10/735,561  
Attorney Docket No. PC25627A

## REMARKS

### I. Status of the Application

This paper responds to a non-final Office action mailed June 7, 2006. This paper cancels claims 1-6, 8, 10, and 13-16 without prejudice or disclaimer and amends claims 7, 9, 11, and 12. Therefore, claims 7, 9, 11, and 12 are currently pending. By action taken here, Applicant in no way intends to surrender any range of equivalents beyond that needed to patentably distinguish the claimed invention as a whole over the prior art. Applicant reserves all such equivalents that may fall in the range between Applicant's literal claim recitations and combinations taught or suggested by the prior art. Applicant reserves the right to file one or more divisional or continuation applications to claim any canceled or unclaimed subject matter.

### II. Amendment of Claims 7, 9, 11, and 12

Applicant has amended independent claims 7 and 9 to recite the administration of (3S,4S)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid or a pharmaceutically acceptable salt thereof to treat fibromyalgia. Applicant has also amended claims 7 and 9 to address claim informalities and to improve readability. In addition, Applicant has amended dependent claims 11 and 12 to eliminate redundant references to (3S,4S)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid. Applicant submits that none of these amendments introduce new matter.

### III. Rejection of claims 1-12 under 35 U.S.C. § 112 ¶2

The non-final Office action rejected claims 1-12 under 35 U.S.C. § 112 ¶2 as allegedly being indefinite. The Office action has objected to the use of "mammal" together with the phrase "including a human," because "this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) required feature of the claims." Applicant has deleted the phrase "including a human" from claims 7 and 9 to clarify that the method is not limited to treating fibromyalgia in humans, but can be used broadly to treat fibromyalgia in mammals.

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The Office action has also objected to the use of the phrase “therapeutically effective amount.” As suggested in the Office action, Applicant has amended claims 7 and 9 to include the phrases “therapeutically effective amount for treating fibromyalgia” and “therapeutically effective amount for treating fibromyalgia and a concomitant disorder.”

In view of the above, Applicant respectfully requests withdrawal of the rejections.

IV. Rejection of claims 1-12 under 35 U.S.C. § 103(a)

The Office action rejected claims 1-12 under 35 U.S.C. § 103(a) as being unpatentable in view of WO 99/21824 and the Merck Manual. According to the Office action, WO 99/21824 describes various cyclic amino acids, including (3*S*,4*S*)-(1-aminomethyl-3,4-dimethylcyclopentyl)-acetic acid, and teaches that such cyclic amino acids may be used to treat pain, among other disorders. The Office action admits that WO 99/21824 is “silent” regarding the treatment of fibromyalgia, but states that the Merck Manual teaches that “fibromyalgia is characterized by pain of the fibrous tissues, muscles, tendons, ligaments, and other sites.” Thus, according to the Office action, one of ordinary skill in the art “would recognize that the pain associated with fibromyalgia would be necessarily treated with the administration of the cyclic amino acid compounds . . . [taught in WO 99/21824 because it] specifically teach[es] that these compounds are effective in the treatment of pain.”

Applicant submits that the Office action has not made out a *prima facie* case of obviousness and therefore the claims of the invention are patentable over WO 99/21824 and the Merck Manual. Although WO 99/21824 teaches that (3*S*,4*S*)-(1-aminomethyl-3,4-dimethylcyclopentyl)-acetic acid is useful for treating pain, Applicant submits that the Merck Manual teaches away from the use of a pain reliever for treating fibromyalgia. Indeed, the Merck Manual states that “[a]spirin 650 mg po q 3 to 4 h or other NSAIDs in full dosages have not generally been shown to be effective in clinical trials but may help individual patients.” Merck Manual at page 482. Instead of using analgesics to treat fibromyalgia, the Merck Manual describes the use of “low-dose tricyclic antidepressants . . . at bedtime [which] may help promote deeper sleep and have modulatory effects on the pain”; injections of lidocaine in combination with a hydrocortisone acetate suspension to treat “incapacitating areas of focal tenderness”; and the use of a “serotonin-specific reuptake inhibitor . . . [which] may alleviate depression and help symptoms.” *Id.* In

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terms of treatment options, the Merck Manual concludes that “[u]ltimately, the best management of PFS is a personalized, comprehensive, ambulatory, patient-motivated and patient-involved program” which suggests that, at present, it is highly unpredictable whether any particular drug, including an analgesic, would be useful in treating fibromyalgia.

In view of the above, Applicant respectfully requests withdrawal of the rejection.

V. Rejection of claims 1-12 for Obviousness-Type Double Patenting

The Office action rejected claims 1-12 for Obviousness-Type Double Patenting over claims 1-15 of U.S. Patent No. 6,001,876 in view of the Merck Manual. Applicant submits that the Office Action has not made out a *prima facie* case of obviousness because the compound (3*S*,4*S*)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid, which is recited in the claims of the present application, is structurally dissimilar to the compounds recited in the claims of the '876 patent. In addition to the lack of di-methyl substitution on the cycloalkyl group, the C-3 carbon atom of the compound of Formula I in the '876 patent is not part of the cycloalkyl group. In contrast, the C-3 carbon atom in (3*S*,4*S*)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid is one of the ring atoms which form the cyclopentyl group.

The Office action also provisionally rejected claims 1-12 for Obviousness-Type Double Patenting over claims 1 and 11 of copending Application No. 10/731,225. Applicant submits that the Office Action has not made out a *prima facie* case of obviousness because the compound (3*S*,4*S*)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid, which is recited in the claims of the present application, is structurally dissimilar to the compounds recited in the claims of the '225 patent application. In addition to the lack of di-methyl substitution on the cycloalkyl group, the C-3 carbon atom of the compound of Formula I in the '225 patent application is not part of the cycloalkyl group. In contrast, the C-3 carbon atom in (3*S*,4*S*)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid is one of the ring atoms which form the cyclopentyl group.

In view of the above, Applicant respectfully requests withdrawal of the rejections.

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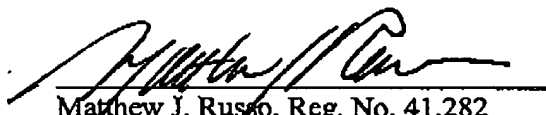
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VI. Conclusion

Applicant believes that no fees are due. However, if any fees are due in connection with the filing of this paper, please charge them to deposit account number 23-0455.

Respectfully submitted,

Date: September 7, 2006



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